

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALLERGAN, INC.,
ALLERGAN PHARMACEUTICALS IRELAND
UNLIMITED COMPANY, and
ALLERGAN USA, INC.

Plaintiffs,

v.

REVANCE THERAPEUTICS, INC. and
ALTHEA, INC. d/b/a AJINOMOTO BIO-
PHARMA SERVICES,

Defendants.

Civil Action No. 21-1411-RGA

MEMORANDUM OPINION

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 ANDREWS, U.S. DISTRICT JUDGE:

Before me is the issue of claim construction of multiple terms in U.S. Patent Nos. 7,354,740 (“the ’740 patent”), 8,409,828 (“the ’828 patent”), 11,124,786 (“the ’786 patent”), 11,203,748 (“the ’748 patent”), 11,326,155 (“the ’155 patent”), 11,033,625 (“the ’625 patent”), 11,147,878 (“the ’878 patent”), 11,285,216 (“the ’216 patent”), and 7,332,567 (“the ’567 patent”) (collectively, “the Asserted Patents”). The parties submitted a Joint Claim Construction Brief (D.I. 141), and subsequently narrowed the issues in advance of the hearing. (D.I. 162; D.I. 167). I heard oral argument on June 28, 2023 (Markman Tr.).¹ After oral argument, Defendants submitted a letter regarding a revised proposed construction for one term. (D.I. 171).

I. BACKGROUND

On October 1, 2021, Plaintiffs filed a complaint against Defendants alleging patent infringement for the ’625 patent, the ’740 patent, the ’828 patent, the ’786 patent, and the ’567 patent. (D.I. 1). On November 24, 2021, Plaintiffs filed their First Amended Complaint additionally alleging infringement of the ’878 patent. (D.I. 16). On December 30, 2022, Plaintiffs filed their Second Amended Complaint additionally alleging infringement of the ’216 patent, the ’748 patent, and the ’155 patent. (D.I. 79). The Asserted Patents describe animal product free formulations of a *botulinum* toxin and processes for purifying the same. (*See, e.g.*, D.I. 79, ¶¶ 16-59).

II. LEGAL STANDARD

“It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312

¹ Citations to the transcript of the argument, which is not yet docketed, are in the format “Markman Tr. ___.”

(Fed. Cir. 2005) (en banc) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.’ Instead, the court is free to attach the appropriate weight to appropriate sources ‘in light of the statutes and policies that inform patent law.’” *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). Of these sources, “the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

“[T]he words of a claim are generally given their ordinary and customary meaning... [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312–13 (citations and internal quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court’s construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which “consists of all evidence external to the

patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

“[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The requirement that patent claims be definite requires that patents be “precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them.” *Nautilus*, 572 U.S. at 909 (cleaned up). Inferring indefiniteness because a claim’s scope is broad, however, is “legally incorrect: ‘breadth is not indefiniteness.’” *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1367 (Fed. Cir. 2017) (quoting *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1341 (Fed. Cir. 2005)). The party raising indefiniteness bears the burden of proving it by clear and convincing evidence. *See BASF*, 875 F.3d at 1365.

III. PATENT CLAIMS AT ISSUE

Plaintiffs are asserting the following 104 claims: ’740 patent claims 1-8; ’828 patent claims 1, 2, 6, and 8; ’786 patent claims 1-6, 8-12, and 14; ’748 patent claims 1-6, 8-12, and 14; ’155 patent claims 1-3, 5-10, 12-17, 10-24, 26, and 27; ’625 patent claims 1-3, 6, 8-11, 13-16, and 19; ’878 patent claims 1, 2, 4-10, 12, 13, 15, 18-20; ’216 patent claims 1-3, 5, 6, 9-13, 16-18, 21-23;

and '567 patent claim 1. (D.I. 172).² The following claims are representative and most relevant for purposes of claim construction:

Claim 6 of the '740 Patent:

6. An APF process for purifying a biologically active *botulinum* toxin, the process comprising the steps of:
 - (a) obtaining a sample of a *botulinum* toxin fermentation culture, wherein the *botulinum* toxin fermentation culture results from a substantially APF process,
 - (b) ***conditioning the clarified culture*** for hydrophobic interaction chromatography;
 - (c) ***contacting a hydrophobic interaction chromatography column resin with the culture sample so as to permit capture of a botulinum toxin by the hydrophobic interaction chromatography column***;
 - (d) washing impurities off the hydrophobic interaction chromatography column;
 - (e) eluting the *botulinum* toxin from the hydrophobic interaction column;
 - (f) conditioning the eluent from hydrophobic interaction column for ion exchange chromatography;
 - (g) loading an ion exchange column chromatography column resin with the conditioned eluent from the hydrophobic interaction chromatography column;
 - (h) washing impurities off the ion exchange chromatography column, and
 - (i) eluting the *botulinum* toxin from the ion exchange column, thereby obtaining a purified biologically active *botulinum* toxin through a process for purifying a *botulinum* toxin which is a substantially APF purification process.

('740 patent at 47:28-51 (disputed terms italicized and bolded)).

Claim 1 of the '828 Patent:

1. An animal product free process for purifying a biologically active botulinum toxin, the process comprising the steps of:
 - (a) preparing a botulinum toxin fermentation culture for passage over chromatography columns, wherein the fermentation culture is animal product free;
 - (b) ***contacting a first chromatography column resin with prepared botulinum toxin fermentation culture, so as to permit capture of a botulinum toxin by the first column, wherein the first chromatography column resin utilizes a first separation mechanism selected from the group consisting of ion exchange, hydrophobic interaction, gel filtration and mixed mode mechanisms***;
 - (c) eluting the botulinum toxin from the first column;
 - (d) loading a second column with eluent from the first column, wherein the second column interacts with eluent from the first column utilizing a second separation mechanism different from the first separation mechanism from the first column

² The Parties expect to file a much-needed case narrowing proposal no later than October 10, 2023. (D.I. 54, ¶ 18).

wherein the second separation mechanism is selected from the group consisting of ion exchange, hydrophobic interaction, gel filtration and mixed mode mechanisms; and
(e) eluting the botulinum toxin from the second column, thereby obtaining a purified biologically active toxin.

('828 patent at 46:42-65 (disputed term italicized and bolded)).

Claim 1 of the '625 Patent:

1. A powder pharmaceutical composition, comprising:
a botulinum toxin, wherein the botulinum toxin is a type A serotype;
a surfactant;
at least one disaccharide selected from the group consisting of sucrose and trehalose; and
a buffer sufficient to maintain a pH of from about 5 to about 7.3 upon reconstitution with sterile normal saline or water;
wherein the composition is suitable for intramuscular or subcutaneous injection following reconstitution with sterile normal saline or water,
wherein the composition is animal protein free, and
wherein the composition retains at least about 75% of the theoretical maximum potency of the botulinum toxin following storage as a powder for three months at below freezing temperature.

('625 patent at 73:38-54 (disputed term italicized and bolded)).

Claim 1 of the '878 Patent:

1. An animal protein free method to stabilize a serotype A Clostridial botulinum neurotoxin, comprising:
(a) compounding an aqueous carrier with two or more non-animal derived non-protein excipients and a biologically active serotype A Clostridial botulinum neurotoxin to form a compounded formulation; and
(b) lyophilizing or vacuum-drying the compounded formulation to thereby provide a stable powdered formulation;
wherein:
the two or more non-animal derived non-protein excipients comprise (i) a surfactant and (ii) a disaccharide selected from the group consisting of trehalose and sucrose;
the powdered formulation retains an initial potency of at least about 50% of the theoretical maximum potency of the botulinum toxin after reconstitution with normal saline or water;
the powdered formulation has a pH from about 5 to about 7.3 after reconstitution with normal saline or water;
the powdered formulation is suitable for intramuscular or subcutaneous administration after reconstitution with normal saline or water; and
the powdered formulation is animal protein free and polysaccharide free.

('878 patent at 71:36-59 (disputed term italicized and bolded)).

Claim 1 of the '216 Patent:

1. A powder pharmaceutical composition comprising:
 - a botulinum toxin, wherein the botulinum toxin is a type A serotype;
 - a surfactant;
 - at least one disaccharide selected from the group consisting of sucrose, lactose, and trehalose; and
 - a buffer sufficient to maintain a pH of from about 5.5 to about 6.5 upon reconstitution with sterile normal saline or water;
 wherein:
 - the composition is suitable for intramuscular or subcutaneous injection following reconstitution with sterile normal saline or water;
 - the composition is animal protein free; and
 - the composition retains at least about 50% of the theoretical maximum potency of the botulinum toxin following storage as a powder for three months at room temperature.***

('216 patent at 71:40-57 (disputed term italicized and bolded)).

Claim 1 of the '567 Patent:

1. A botulinum toxin serotype A (BoNT/A) substrate, comprising:
 - (a) a donor fluorophore;
 - (b) an acceptor fluorophore having an absorbance spectrum overlapping the emission spectrum of said donor fluorophore; and
 - (c) a BoNT/A recognition sequence comprising a cleavage site, wherein said cleavage site intervenes between said donor fluorophore and said acceptor fluorophore;***wherein, under the appropriate conditions, resonance energy transfer is exhibited between said donor fluorophore and said acceptor fluorophore.***

('567 patent at 107:42-53 (disputed term italicized and bolded)).

IV. CONSTRUCTION OF AGREED-UPON TERMS

I adopt the following agreed-upon constructions:

Claim Term	Claims	Construction
" <i>botulinum</i> toxin fermentation culture"	'828 Patent claim 1; '740 Patent, claims 1, 2, and 6.	"a fermentation medium in which a <i>Clostridium botulinum</i> bacterium has been fermented so that the bacterium has released <i>botulinum</i> toxin into the medium"

“the culture”	’740 Patent, claims 1, 2, and 6.	The term “the culture” refers to the “ <i>botulinum</i> toxin fermentation culture” term appearing earlier in the claim, and the parties have agreed upon the construction of “ <i>botulinum</i> toxin fermentation culture”
“at least one impurity protein”	’786 patent, claim 1; ’748 patent, claim 1; ’155 patent, claim 1, 9, 15, 23.	“at least one non- <i>botulinum</i> toxin protein, including hemagglutinin and non-toxin non-hemagglutinin proteins” (D.I. 162-1)
“900 kDa BoNT/A” / “900 kDa BoNT/A complex”	’748 Patent, claim 1; ’155 Patent, claims 1, 9, 15, and 23.	“900 kDa BoNT/A complex” (D.I. 162-1)
“substantially APF process”	’740 patent, claims 1, 6.	“a process where animal products are present at a level of less than one percent by weight” (D.I. 167)
“animal product free”	’828 patent, claim 1.	“the absence or substantial absence of blood derived, blood pooled, and other animal derived products or compounds” (D.I. 167)

V. CONSTRUCTION OF DISPUTED TERMS

1. “clarified culture” (claims 2 and 6 of the ’740 patent)

- a. *Plaintiffs’ proposed construction*: Plain and ordinary meaning, which is a “fermentation culture from which gross impurities have been removed.”
- b. *Defendants’ proposed construction*: “*botulinum* toxin fermentation culture from which gross impurities have been removed without using any acid precipitation step.” (D.I. 171).
- c. *Court’s construction*: “Fermentation culture from which gross impurities have been removed.”

The parties dispute whether a “clarified culture” can be obtained only via a filtration process of the fermentation culture. (D.I. 141 at 12). Plaintiffs argue that a clarified culture would be understood with respect to its plain and ordinary meaning. *Id.* According to Plaintiffs, the plain

and ordinary meaning is a fermentation culture that has been filtered to remove “gross impurities,” resulting in “a clear solution referred to [as] a clarified culture.” (’740 patent at 30:1-3). The ’740 patent describes multiple methods of obtaining a clarified culture from a fermentation culture, including filtration using a single layer depth filter, centrifugation, and acid precipitation. (*Id.* at 28:13-17; 25:37; 34:5-8). Plaintiffs contend that regardless of the method used to produce the clarified culture, the claim is defined by what it is — not the process used to obtain it. (D.I. 141 at 13).

Defendants counter that a culture can only become clarified once the fermentation culture has been filtered to remove gross impurities, such as lysed bacteria or other media nutrients. (*Id.* at 14; ’740 patent at 8:62-67). Defendants argue that, based on intrinsic evidence in the specification, the removal of the gross impurities must be done with a single layer depth filter because “filtration” and “clarified culture” are consistently used together throughout the specification, implying that filtration is necessary to achieve the clarified culture. (D.I. 141 at 15, 17). Defendants state, in relation to other methods of obtaining the clarified culture, that “the fact that cultured cells are physically capable of being centrifuged does not mean that process results in a ‘clarified culture.’” (*Id.* at 16). Defendants further contend that a clarified culture cannot be obtained through a method involving acid precipitation because the specification disparages this method by describing “drawbacks” including “low resolution, low productivity, difficulty to operate, difficulty to control and/or validate, and difficulty to scale-up or scale-down.” (*Id.* at 17; ’740 patent at 10:48-52). During oral argument, Defendants narrowed their argument to only the disavowal of acid precipitation as a method of achieving a clarified culture. (Markman Tr. at 25:16-23 (“[T]o the extent that the Court is inclined to include maybe other ways to achieve a clarified culture, remove gross impurities, the Court should expressly remove acid precipitation as one of

those mechanisms...)). I asked Defendant to submit a proposed construction to that effect, and they did. (*See* D.I. 171).

I agree with Plaintiffs' construction of "clarified culture." The '740 patent's specification describes acid precipitation as one of multiple methods of removing the impurities from a fermentation culture, all of which result in a clarified culture. I cannot conclude that Plaintiffs' inclusion of certain "drawbacks" to acid precipitation in the specification expressly disavows the use of acid precipitation to make the claimed clarified culture.

Disavowal requires the specification to clearly show that the "invention does not include a particular feature." *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001). The specification must be "both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer." *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1322 (Fed. Cir. 2012) (internal citation omitted). To find disavowal of claim scope through disparagement of a particular feature, I must determine whether "the specification goes well beyond expressing the patentee's preference ... [such that] its repeated derogatory statements about [a particular embodiment] reasonably may be viewed as a disavowal." *Chicago Bd. Options Exchange, Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1372 (Fed. Cir. 2012); *see also Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 513 (Fed. Cir. 2015).

The '740 patent specification does not meet the high bar for disavowal. Acid precipitation is not repeatedly disparaged throughout the specification — the drawbacks are only mentioned once. *See Openwave Systems, Inc.*, 808 F.3d at 517. If anything, the specification's mention of drawbacks merely describes a preference for filtration over acid precipitation. In fact, the specification highlights certain advantages of acid precipitation, including "remov[ing] additional impurities" and "virus inactivation." ('740 patent at 34:11-14). The specification's discussion of

acid precipitation does not rise to the level of repeated and clear disparagement required to disavow acid precipitation from the claim's scope. A preferred method or embodiment does not disclaim other embodiments. *Epistar Corp. v. Int'l Trade Com'n*, 566 F.3d 1321, 1337 (Fed. Cir. 2009). A POSA would understand that any of the methods mentioned in the specification, including filtration, centrifugation, or acid precipitation, could be used to obtain the clarified culture from the fermentation culture. The term has its plain and ordinary meaning. I think Plaintiffs' formulation of that plain and ordinary meaning might be helpful to the jury. I therefore adopt it.

2. "conditioning the clarified culture" (claims 2 and 6 of the '740 patent)

- a. *Plaintiffs' proposed construction*: plain and ordinary meaning
- b. *Defendants' proposed construction*: indefinite
- c. *Court's construction*: plain and ordinary meaning

Defendants contend that there are three reasons that this term is indefinite.

First, Defendants argue that the '740 patent does not provide guidance as to the steps for "conditioning" a culture. (D.I. 141 at 45). The patent specification gives an example of conditioning the clarified culture by the addition of "4M NaCl." '740 patent at 39:4-8. Defendants argue, however, that this example is not enough as the specification does not provide any other information about what constitutes conditioning, which could include using different salts, different concentrations, and/or adjusting the pH. (D.I. 141 at 45). Plaintiffs argue that "conditioning" refers to a well-known process of which a POSA would be aware. (*Id.* at 47). During the oral argument, Defendants agreed that "conditioning" is a term of art. (Markman Tr. at 35:7-11).

While the claim language may be broad, it is not indefinite. *See BASF*, 875 F.3d at 1367 ("Breadth is not indefiniteness"). The term "conditioning" by itself does not render the term

indefinite. Although the claim language and specification do not contain detailed explanations regarding every parameter involved in conditioning a culture for interaction with a chromatography column, they do not necessarily have to. “Conditioning” appears to be a term of art that a POSA would understand. The question of whether a POSA would know how to use the full scope of the term is not an indefiniteness issue.

Second, Defendants argue that it is unclear what “the clarified culture” is referring to in claims 2 and 6 because there is no antecedent basis. (D.I. 141 at 46). Similarly, Defendants contend that the step of “conditioning the clarified culture” does not align with the other steps in the claims. For example, claim 6 of the ‘740 patent requires as its first three steps:

“(a) obtaining a sample of a *botulinum* toxin fermentation culture...;
 (b) conditioning the clarified culture for hydrophobic interaction chromatography; [and]
 (c) contacting a hydrophobic interaction chromatography column resin with the culture sample...”

According to Defendants, the culture sample in step (b) is not sufficiently linked to the sample disclosed in steps (a) and (c) because a POSA would not know whether the clarified culture in step (b) is independent of the fermentation culture in step (a), if the fermentation culture sample in step (a) is already clarified, or if the culture sample in step (c) is the same clarified culture as in step (b).

As Plaintiffs point out, however, the specification states that the fermentation culture is “preferably” the clarified culture such that a POSA would know to what the clarified culture in step (b) is referring. (*Id.* at 48; ‘740 patent at 14:7-10 (“the sample of a botulinum toxin fermentation culture (medium) is preferably a sample of a clarified culture of the fermentation medium.”)). It is true that “the clarified culture” is the first time “clarified culture” appears in the

claim, and, thus, “the clarified culture” lacks antecedent basis. The lack of an antecedent basis “may, but does not necessarily, render a claim indefinite.” *In re Downing*, 754 F. App’x 988, 996 (Fed. Cir. 2018). A POSA would know that the clarified culture in step (b) is the “fermentation culture [sample in step (a)] from which gross impurities have been removed” because the POSA would understand a “clarified culture” sample comes from the fermentation sample (by definition) and because the specification tells the POSA the fermentation culture sample is preferably a clarified culture sample. Step (b) describes conditioning this clarified culture sample, and the resulting culture sample is applied to the chromatography column in step (c). Here, the lack of antecedent basis does not render the claim indefinite because “the clarified culture” does apprise a POSA of term’s scope and serves the notice function. *See id.*

Third, Defendant argues that the claims do not provide reasonable certainty whether “conditioning the clarified culture” requires only one step – conditioning – or two steps – clarifying and conditioning. (D.I. 141 at 47). The step of clarifying the culture is not claimed; only conditioning the clarified culture is claimed. This does not, however, render the claims indefinite. The parties have agreed that “*botulinum* toxin fermentation culture” means “a fermentation medium in which...the bacterium has released *botulinum* toxin into the medium.” I have further construed “clarified culture” to mean the “fermentation culture from which gross impurities have been removed.” Based on these constructions and the specification’s statement that the fermentation culture is preferably a clarified culture, a POSA would know that the “clarified culture” in step (b) is the “fermentation culture” from step (a) that has been clarified.

While claim 6 may not be a beacon of clarity, Defendants have not shown that the disputed term is indefinite. Therefore, I find that this term has its plain and ordinary meaning.

3. **“contacting a hydrophobic interaction chromatography column resin with the culture sample so as to permit capture of a botulinum toxin by the hydrophobic interaction chromatography column” / “contacting a first chromatography column resin with prepared botulinum toxin fermentation culture, so as to permit capture of a botulinum toxin by the first column, wherein the first chromatography column resin utilizes a first separation mechanism selected from the group consisting of ion exchange, hydrophobic interaction, gel filtration and mixed mode mechanisms” (claims 1 and 6 of the ’740 patent; claim 1 of the ’828 patent)**

- a. *Plaintiffs’ proposed construction:* plain and ordinary meaning
- b. *Defendants’ proposed construction:* indefinite
- c. *Court’s construction:* plain and ordinary meaning.

Defendants contend that these terms are indefinite because their accused process subjects the fermentation culture to additional processing before chromatography, and the claims only require contacting the hydrophobic interaction chromatography (HIC) column with a fermentation medium into which botulinum toxin has been released. (D.I. 141 at 51). Defendants also argue that a POSA would not have reasonably certainty as to the scope of the claims and what would constitute the “sample.” (*Id.* at 52). It seems to me that Defendants are simply making a non-infringement argument rather than attempting to meaningfully construe the terms that do have a plain meaning to a POSA for processing the “culture” to “permit capture of a botulinum toxin.” This is more appropriately resolved at summary judgment, and I will not find the claim terms indefinite. Therefore, I will construe this term to have its plain and ordinary meaning.

4. **“retains...potency” limitations (claims 1 and 15 of the ’625 patent; claims 1, 8, 13 and 20 of the ’878 patent; claims 1, 16, 17, and 23 of the ’216 patent)**

- a. *Plaintiffs’ proposed construction:* Plain and ordinary meaning.
- b. *Defendants’ proposed construction:* Indefinite.
- c. *Court’s construction:* Plain and ordinary meaning.

Defendants argue that the “retains...potency” terms are indefinite because a POSA would not understand when or how to measure the potency of the powdered compositions. (D.I. 141 at 71). Plaintiffs respond that a POSA would understand how and when to measure potency from the claim language and intrinsic evidence. (*Id.* at 73-75). Both parties rely on the opinions of their experts in support of their positions which raise factual issues that are not appropriate for claim construction. (Markman Tr. at 63:4-10 (“For this particular argument...it seems to me like this is an argument where you're relying on your expert...and relying on your expert for, Here are various methods of doing these things. You get different results. Those seem to me like kinds of things that are not really good at claim construction.”)). The terms have their plain and ordinary meaning. Defendants are correct that if there are uncertainties in how to measure potency, that uncertainty could be the basis for an argument that the limitation is indefinite. But that is an issue for another day.

5. “wherein, under the appropriate conditions, resonance energy transfer is exhibited between said donor fluorophore and said acceptor fluorophore” (claim 1 of the '567 patent)

- a. *Plaintiffs' proposed construction*: Plain and ordinary meaning.
- b. *Defendants' proposed construction*: Indefinite.
- c. *Court's construction*: Plain and ordinary meaning.

During oral argument, the parties agreed to meet and confer on this term and address indefiniteness during expert discovery. (Markman Tr. at 76:24-78:9). The parties will also advise the Court if they are able to reach an agreement on the meaning of this term. In the interim, I assume that the term has its plain and ordinary meaning.

VI. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.